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Intellectual Property Law

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IAP15 Rec'd PCT/PTO 0 6 JUL 2006

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July 6, 2006

Via Express Mail (EV 725787049 US)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Title:

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"Express Mail" mailing label No. EV 725787049 US

Date of Deposit: July 6, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name: Elie H. Gendloff

Signature:

Re: U.S. Patent Application Serial No. 10/542,958

(U.S. National Phase Entry of PCT/US04/01773)

USE OF MYCOBACTERIAL VACCINES IN CD4<sup>+</sup> OR CD8<sup>+</sup> LYMPHOCYTE-DEFICIENT MAMMALS

Inventors: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov,

Vasan Sambandamurthy and Sheldon Morris

Our File: 96700/1031

Dear Sir:

Pursuant to our receipt of a "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)," enclosed please find the following documents for filing with the above-identified patent application in the names of William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov, Vasan Sambandamurthy and Sheldon Morris, entitled USE OF MYCOBACTERIAL VACCINES IN CD4<sup>+</sup> OR CD8<sup>+</sup> LYMPHOCYTE-DEFICIENT MAMMALS, comprising the following:

- a copy of a "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" dated March 13, 2005 for the above-identified case (3 pages);
- 2. a "Reply to Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US)" with a two-month extension of time requested therein (4 pages);

- 3. a Fee Transmittal, Form PTO/SB/17 (1 page);
- 4. an executed Declaration in compliance with 37 C.F.R. § 1.497(a) and (b) (5 pages total);
- 5. a "Declaration for Utility Patent Application Under 37 C.F.R. 1.63" executed by deceased inventor Stoyan Bardarov's legal heir (2 pages);
- 6. a Sequence Listing in both computer-readable form (1 diskette) and written form (10 pages);
- 7. an Information Disclosure Statement, Forms PTO/SB/08A (1 page) and PTO/SB/08B (4 pages) with 33 non-US patent references attached thereto;
- 8. an Amster Rothstein & Ebenstein LLP check in the amount of \$290 to cover the two-month extension of time fee and the late declaration surcharge, claiming small entity status; and
- 9. a return receipt postcard.

Small entity status was previously established and is still proper.

Please acknowledge receipt of the enclosed papers by stamping the enclosed postcard and returning same to us.

Respectfully submitted,

07/13/2006 GFREY1 00000122 10542958

65.00 OP 225.00 OP Amster, Rothstein & Ebenstein LLP

Attorneys for Applicants

90 Park Avenue

New York, NY 10016

212 336 8000

Dated: New York, New York

July 6, 2006

Elie H. Gendloff

Registration No. 44,704

PTO/SB/17 (01-06)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).  FEE TRANSMITTAL  For FY 2006		(8)	Complete if Known					
		<ul> <li>Application Nu</li> </ul>	ımber 10	10/542,958				
		Filing Date	Ja	January 23, 2004 (I.A.)				
		First Named In	ventor W	William R. Jacobs, Jr.				
Applicant claims small entity	status Soc 37 CER 1 27	Examiner Nam	ne to	be determined				
		Art Unit	to	be determined				
TOTAL AMOUNT OF PAYMENT	(\$) 290	Attorney Dock	et No. 96	3700/1031				
METHOD OF PAYMENT (che	METHOD OF PAYMENT (check all that apply)							
Check Credit Card Money Order None Other (please identify):								
Deposit Account Deposit Account Number: 01-1785 Deposit Account Name: AMSTER ROTHSTEIN & EBENSTEIN LLP								
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)								
Charge fee(s) indica	ated below	Chai	rge fee(s) ind	dicated below, exce	pt for the filing fee			
Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card								
WARNING: Information on this form information and authorization on PTC		d information should	not be inclua	ed on this form. Prov	ide credit card			
FEE CALCULATION (All the	fees below are due upo	n filing or may be	e subject t	o a surcharge.)				
1. BASIC FILING, SEARCH,		ES						
Fil	LING FEES SE Small Entity	EARCH FEES	EXAMIN	NATION FEES				
Application Type Fee		Small Entity e (\$) Fee (\$)	<u>Fee (\$)</u>	Small Entity Fee (\$)	Fees Paid (\$)			
Utility 30		00 250	200	100				
Design 20	00 100 10	00 50	130	65				
Plant 20	00 100 30	00 150	160	80				
Reissue 30	00 150 50	00 250	600	300				
Provisional 20	00 100	0 0	0	0				
2. EXCESS CLAIM FEES					mall Entity			
Fee Description Each claim over 20 (includ	ling Raicenas)			<u>Fee (\$)</u> 50	Fee (\$) 25			
Each independent claim ov				200	100			
Multiple dependent claims				360	180			
• •		Fee Paid (\$)		Multiple Depe	endent Claims			
- 20 or HP =	x=_			Fee (\$)	Fee Paid (\$)			
HP = highest number of total claims Indep. Claims Extra	· · ·	Fee Paid (\$)						
- 3 or HP =	x =							
HP = highest number of independent claims paid for, if greater than 3.								
3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer								
listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50								
sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).  Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)								
- 100 = / 50 = (round <b>up</b> to a whole number) x =								
4. OTHER FEE(S)  Non-English Specification, \$130 fee (no small entity discount)  Fees Paid (\$)								
Other (e.g., late filing surcharge): late declaration surcharge and two-month ext. of time fee - small entity status \$290								
SUBMITTED BY								
Signature (C)	, un	Registration No. (Attorney/Agent)	44,70	)4 Telephone	212-336-8000			
Name (Print/Type) Flie H. Gond	المام الا	[ (Attorney/Agent)	1 1,1	Date	July 6, 2006			

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



#### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/542,958	William R Jacobs JR.	96700/1031
		INTERNATIONAL APPLICATION NO.

1912 AMSTER, ROTHSTEIN & EBENSTEIN LLF 90 PARK AVENUE NEW YORK, NY 10016 96700/1031

INTERNATIONAL APPLICATION NO.

PCT/US04/01773

I.A. FILING DATE PRIORITY DATE

01/23/2004 01/24/2003

Date Mailed: 03/13/2006

# NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 07/21/2005
- Copy of the International Search Report filed on 11/14/2005
- Copy of IPE Report filed on 11/14/2005
- Preliminary Amendments filed on 07/21/2005
- U.S. Basic National Fees filed on 07/21/2005
- Priority Documents filed on 07/21/2005
- Specification filed on 07/21/2005
- Claims filed on 07/21/2005
- Abstracts filed on 07/21/2005
- Drawings filed on 07/21/2005

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$65 for a Small Entity:

- \$65 Surcharge.
  - This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
  - A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/542.958	PCT/LISO4/01772	06700/1021

942,958 PCT/US04/01773

FORM PCT/DO/EO/905 (371 Formalities Notice)

### IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

Application No. :

10/542,958

Confirmation No. 2060

Applicant

: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardarov,

: Vasan Sambandamurthy and Sheldon Morris

Filed

January 23, 2004 (I.A.)

TC/A.U.

: Not determined

Examiner

Not determined

Docket No.

96700/1031

Customer No.

1912

"Express Mail" mailing label No. EV 725787049 US

Date of Deposit: July 6, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name: Elie H. Gendloff

Signature:

# REPLY TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Reply is to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated March 13, 2006 in the above-identified application. Applicants hereby request a two-month extension of time for filing this Reply, and include with the enclosed check the small entity fee of \$225 to cover the two-month extension of time. With that extension, this Reply is due July 13, 2006 and is timely filed.

#### Oath or Declaration

Enclosed herewith is a Declaration of the inventors, executed by Inventors Jacobs, Hsu, Sambandamurthy, and Morris, for the above-identified patent application believed to be in compliance with 37 C.F.R. 1.497(a) and (b). Also included is a Declaration for

Utility Patent Application Under 37 C.F.R. 1.63 for deceased inventor Stoyan Bardarov, executed by inventor Bardarov's heir, Svetoslav Bardarov.

# Sequence Requirements

Enclosed herewith a sequence listing in both paper and computer-readable forms for the above-identified patent application, previously filed in the international stage of this application, PCT/US04/01773. The content of the sequence listing information recorded in computer readable form is identical to the written (on paper) sequence listing. This sequence listing includes no new matter.

## Information Disclosure Statement

Enclosed herewith are Forms PTO/SB/08A (1 page) and PTO/SB/08B (4 pages) and copies of the 33 non-US patent references listed on Forms PTO/SB/08A and PTO/SB/08B.

#### **Amendment**

Please enter the following amendment to the instant patent application.

Appl. No. PCT/US2004/001773 (filing under 35 U.S.C. 371) Reply to Notification of Missing Requirements dated July 6, 2006

# **Specification Amendment**

Please enter the enclosed sequence listing into this patent application.

#### Remarks

It is believed that the enclosed \$290.00, covering the late Oath or Declaration surcharge and a two month extension of time (small entity), is all that is required with this Reply. However, if there are unanticipated fees required to maintain pendency of this application, the USPTO is authorized to withdraw the payment for those fees from Deposit Account 01-1785.

# Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP Attorneys for Applicant 90 Park Avenue New York, NY 10016 (212) 336-8000

Dated: New York, New York

July 6, 2006

Elie H. Gendloff

Registration No.: 44,704